McGill
Faculty of Engineering

BIEN 675- Process Analytical Technologies and Data Science
Term- Fall 2023

Class Schedule	Tuesday, 8:35 am to 11:25 am
Location	DUFF 507/509
Instructor	Dr. Rupa Haldavnekar McConnel Engineering Building, Room 707 E 3480 University Street, Montreal
Email	rupa.haldavnekar@mcgill.ca
Office Hours	By Appointment, in person or on zoom

Background and Course Description: Process Analytical Technology (PAT) is a framework for the design of pharmaceutical manufacturing processes that incorporates scientific and risk management tools to generate a thorough understanding of a process oriented to product quality. PAT enables identification, monitoring and control of critical process parameters (CPPs) that affect the critical quality attributes (CQAs) of pharmaceuticals. This course introduces PAT and Quality by Design (QbD) in the area of manufacturing biologics. Key topics in the course include CPP, CQA, risk assessment, analytical tools used in the production of biologics. The course also covers basic principles for Design of Experiments (DOE). This course introduces students to the role of PAT in process modeling as well as process control including data management as applied to the design of advanced industrial biomanufacturing processes.

Course outline: The course is designed to expose bioengineering students to Process Analytical Technologies (PAT) concepts in the field of biomanufacturing under the framework of Quality by Design (QbD), a solid trend in the biomanufacturing industry to design and operate more effectively upstream and downstream unit operations for cost-effective manufacturing of biologics and biological medicines. Featured topics include Introduction to Process Analytical Technologies (PAT) and Quality by Design (QbD)- Concept of Critical Quality Attributes (CQA)/Critical Process Parameters (CPP)-Concept of Design Space-Risk Analysis-Design of Experiments (DoE). Analytical Technologies for Biologics and Biologic Medicines. Process Analytical Technologies for Biomanufacturing: At-line, On-line, Off-line monitoring, process control. Scale down systems for process validation. Data processing, data modelling as well as Process data management and secured storage.

This course is designed to combine lectures, seminars, interactive classroom session as well as visit to operational sites that will provide students with an overview of both theory and practice. Lectures will be structured around defining the key concepts, current challenges, and optimization of Process Analytical Technologies in a biomanufacturing process. Emphasis will be placed on conceptual theory behind these topics and applications to reach the required product quality and design of optimal biomanufacturing processes. Students will prepare and present assigned literature review, case studies and team projects on a broad range of process analytical technologies applied to processing of biologics at the mid-term and final part of this course.

Course material:

- Undey et al., 2012. PAT Applied in Biopharmaceutical Process Development and Manufacturing, CRC Press, Biotechnology and Bioprocessing Series, Vol. 33.
- Process Control, Intensification, and Digitalisation in Continuous Biomanufacturing (EPDF ISBN: 978-3-527-82732-9)
- Process Analytical Technology: Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries, Second Edition, Edited by Katherine A. Bakeev ISBN: 978-0-470-72207-7
- Bioprocess Engineering: Basic Concepts – Michael Schuler and Kargi (available in McGill Library/ebook)
- Biochemical engineering fundamentals / James E. Bailey, David F. Ollis. (Available in McGill Library/ebook)
- Additional reading materials and lecture notes will be posted regularly on myCourses.
- There is no required textbook. Required reading materials (consisting of selected original research papers and review articles), lecture slides and assignments will be posted on the McGill MyCourses.
- Recommended reference case studies:
    - A-Mab: A case study in Bioprocess Development CMC Biotech working Group V.2.1 October 2009
    - A-VAX: Applying Quality by Design to Vaccines CMC-Vaccines Working Group May 2012

Course evaluation and Assessment:

- Active Participation - 10 %
- Mid-Term Team Presentation and Report – 25%
- Interactive Sessions / Assignments – 30 %
- Final Exam – 35 %

Course participation: Students are recommended to be present during all the lectures, as their course participation will contribute to the total grade. Participation will also include active class discussion.

Assignments: Students can work in teams to generate the solutions or information requested, but the assignments will be presented and graded individually. The assignments will be based on in-class interactive sessions focussed on PAT data analytics. Assignment reports to be submitted in MyCourses and will be due before next class.

Mid-Term Team Presentation: Students will select a topic related to PAT and prepare a 20-minute presentation. Students will work in teams of four/ five (4 / 5). The choice of team will be left to the preference of the students, but it will be compulsory to work in teams. The topics must be approved by the instructor(s). Note: More details on presentation format and content will be provided after the start of the course.

Final Exam:

- Type of assessment**:** Individual written examination on the topics covered in the course.

- Exam registration requirements: The exam requires submission of all assignments and study reports and a passing average grade in quizzes.
- Re-exam: Re-exam as ordinary exam. If the requirements are not met a report on a given topic must be handed in no later than 2 weeks before the re-exam.

Learning Objectives:

Participants enrolled in this course will:

- Have a fundamental understanding of process analytical principles (PAT) and operations (KB.3, KB.7).
- Be able to choose and apply appropriate analytical methods for specific products in particular processing steps (PA.1, PA.2, IT.1, IT.3).
- Understand the principles and benefits of PAT and Quality by Design (QbD) in biomanufacturing (KB.4, KB.8).
- Describe specific technologies used at different steps associated with PAT processing (KB.7, PA.1, IT.1).
- Describe possible challenges in analytical technologies and identify solutions (KB.7, IT.1, CS.1, CS.3)
- Describe how PAT can be applied to assess the critical quality attributes of product of purity (KB.7, KB.8, PA.3, PA.4).
- Apply PAT principles for understanding and optimization and design of biomanufacturing process (IN.1, IN.2, DE.1, DE.2, DE.3, DE.4, IT.2).
- Process data acquisition, management and treatment for process monitoring and control in manufacturing of biologics (IN.1, IN.2, DE.1, DE.2).
- Understand the principle of Digital Twin for design of biomanufacturing process (PA3. PA4, DE.4, IT.2).
- Further improve professional development through practicing written communication skills (CS.1, CS.2, CS.4, LL.1, LL.2).

Preliminary Course Schedule (Subject to Change without Notice):

Week of	Description	In Class Interactive Sessions
Sept 5	Introduction and course organisation. Overview of Process Analytical Technologies (PAT) and Quality by Design (QbD) for biomanufacturing	
Sept 12	The QbD approach for manufacturing of biologics- CQA	Intro to JMP, and introduction to statistical insights
Sept 19	CPP, Design space, DOE	Analysis of Variance
Sept 26	PATs used for biologics manufacturing- 1	DOE, predictive modelling
Oct 3	PATs used for biologics manufacturing- 2	Functional data analysis
Oct 10	**Fall Beak – No Lecture**	
Oct 17	**Mid-Term Student Presentations**	
Oct 24	PAT data analysis with chemometrics	Non-Linear regression modelling
Oct 31	Scale-down systems for process validation	Data analysis in formulation
Nov 7	**Guest Seminar**	
Nov 14	PAT and Process Control	Statistical process control
Nov 21	PAT and Process Modelling	
Dec 5	Process data management, Storage and Security	(Visit to biomanufacturing lab to demonstrate Scale-Down system)

Teaching and learning methods:
Delivery of material in lecture format (40%)
Group work, active learning, seminars (30%)
Demonstrations, Interactive session, experiments, simulations (30%)

Language of Written Work:
In accord with McGill University's Charter of Students' Rights, students in this course have the right to submit in English or in French any written work that is to be graded.

Academic Integrity:
McGill University values academic integrity. Therefore all students must understand the meaning and consequences of cheating, plagiarism and other academic offences under the Code of Student Conduct and Disciplinary Procedures (see www.mcgill.ca/students/srr/honest/ for more information).

Disabilities:

If you have a disability, please contact the instructor to arrange a time to discuss your situation. It would be helpful if you contact the Office for Students with Disabilities at (514) 398-6009 before you do this.

COVID-19-related course adaptations for BIEN675:

Lectures:

All lectures will be in person. This may be subject to change based on provincial and university health guidelines**.** *Exception:* Guest presentations provided by speakers off-campus due to their unavailability to come in person